

LABEL, IN PART: "10 cc Size * * * Hyposols Liver Solution U. S. P."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be liver injection, a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the official standard since it was not sterile.

DISPOSITION: December 20, 1944, and April 9, 1945. No claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

1610. Adulteration of isotonic solution of three chlorides and dextrose in isotonic solution of sodium chloride. U. S. v. 26 Flasks of Isotonic Solution of Three Chlorides and 38 Flasks of Dextrose in Isotonic Solution of Sodium Chloride. Default decree of condemnation and destruction. (F. D. C. No. 15282. Sample Nos. 6385-H, 6386-H.)

LIBEL FILED: February 16, 1945, Southern District of New York.

ALLEGED SHIPMENT: On or about October 16 and 25, 1944, by Readyflask, Inc., from Lakewood, Ohio.

PRODUCT: 26 1,000-cc. flasks of *isotonic solution of three chlorides* and 38 1,000-cc. flasks of *dextrose in isotonic solution of sodium chloride*, at New York, N. Y.

NATURE OF CHARGE: Adulteration, Section 501 (b), the articles purported to be and were represented as "No. 3—Sterile Isotonic Solution of Three Chlorides for Parenteral Use" and "Dextrose and Sodium Chloride Injection," drugs the names of which are recognized in the United States Pharmacopoeia, an official compendium, but their quality and purity fell below the official standards since they were contaminated with undissolved material.

DISPOSITION: May 17, 1945. No claimant having appeared, judgment of condemnation was entered and the products were ordered destroyed.

1611. Adulteration of water for injection and solution of sodium citrate. U. S. v. 31 Packages of Water for Injection and 188 Ampuls and 476 Ampuls of Solution of Sodium Citrate. Decrees of condemnation and destruction. (F. D. C. Nos. 15359, 15633, 16209. Sample Nos. 3820-H, 24148-H, 24274-H.)

LIBELS FILED: Between March 8 and May 24, 1945, District of New Jersey, Eastern District of Louisiana, and Northern District of Texas; amended libel filed March 20, 1945, Eastern District of Louisiana.

ALLEGED SHIPMENT: Between the approximate dates of June 13, 1944, and February 7, 1945, by Sharp and Dohme, Inc., from Philadelphia, Pa.

PRODUCT: 31 packages, each containing 25 ampuls, of *water for injection* at Trenton, N. J., and 188 ampuls and 476 ampuls of *solution of sodium citrate* at New Orleans, La., and Dallas, Tex., respectively.

LABEL, IN PART: "Water for Injection U. S. P. XII," or "50-cc. Size Ampul Sterile Anticoagulant Solution of Sodium Citrate U. S. P. XII 2½ Per Cent For Parenteral Use."

NATURE OF CHARGE: Adulteration, Section 501 (b), the articles purported to be and were represented as drugs the names of which are recognized in the United States Pharmacopoeia, an official compendium, but their quality and purity fell below the official standards in that they were contaminated with undissolved material.

DISPOSITION: Between May 12 and June 25, 1945. The sole intervener for the Louisiana lot having consented to the entry of a decree, and no claimant having appeared for the other lots, judgments of condemnation were entered and the products were ordered destroyed.

1612. Adulteration of dextrose in isotonic solution of sodium chloride. U. S. v. 33 Cartons and 72 Flasks of Dextrose in Isotonic Solution of Sodium Chloride. Default decrees of destruction. (F. D. C. Nos. 15361 to 15363, incl. Sample Nos. 27422-H, 29313-H, 29314-H.)

LIBELS FILED: March 26 and April 20, 1945, District of Utah and Western District of Washington.

ALLEGED SHIPMENT: On or about February 7, 1945, by the Cutter Laboratories, from Berkeley, Calif.

PRODUCT: 33 cartons, each containing 6 flasks, of *dextrose in isotonic solution of sodium chloride* at Seattle, Wash., and 72 flasks of the same product at Salt Lake City, Utah.

LABEL, IN PART: (Flask label) "Saftiflask * * * Dextrose 5% W/V in Isotonic Solution of Sodium Chloride"; (carton label) "A safe, sterile, pyrogen-free solution." An enclosed circular gave directions for the use of "Cutter Intravenous Solutions in Saftiflasks."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be "Dextrose and Sodium Chloride Injection," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the official standard since it contained undissolved material.

DISPOSITION: June 2 and September 20, 1945. No claimant having appeared, judgments were entered ordering that the Seattle lot be condemned and destroyed and that the Salt Lake City lot be destroyed.

1613. Adulteration and misbranding of estrogenic material in oil. U. S. v. 470 Ampuls of Estrogenic Material in Oil. Default decree of condemnation and destruction. (F. D. C. No. 15806. Sample No. 4117-H.)

LIBEL FILED: On or about April 14, 1945, District of New Jersey.

ALLEGED SHIPMENT: On or about March 9, 1945, from Philadelphia, Pa., by the Associated Ross-Good Laboratories.

PRODUCT: 470 ampuls of *estrogenic material in oil* at Penns Grove, N. J.

LABEL, IN PART: "Estrogenic Material in oil * * * This Estrogenic Material contains—Estradiol, Estrone and other Estrogenic factors of Pregnant Mares Urine."

NATURE OF CHARGE: Adulteration, Section 501 (d), an oil solution of estrogenic material consisting almost entirely of estradiol had been substituted for an oil solution of estrogenic material containing estradiol, estrone, and other estrogenic factors as they occur in pregnant mares' urine.

Misbranding, Section 502 (a), the label statement, "This Estrogenic Material contains—Estradiol, Estrone and other Estrogenic factors of Pregnant Mares Urine," was misleading since it represented and implied that the estrogenic material in the article was estrogenic material as it occurs naturally in pregnant mares' urine, whereas it was not.

DISPOSITION: May 25, 1945. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1614. Adulteration and misbranding of Duchex. U. S. v. 22 Dozen Packages of Duchex. Default decree of condemnation and destruction. (F. D. C. No. 15296. Sample No. 13808-H.)

LIBEL FILED: On or about February 22, 1945, Northern District of Ohio.

ALLEGED SHIPMENT: On or about December 21, 1944, by Hachmeister, Inc., from Pittsburgh, Pa.

PRODUCT: 22 dozen packages of *Duchex* at Cleveland, Ohio. Examination of a sample showed that the article was not germicidal when used in accordance with the directions appearing on its label.

LABEL, IN PART: "Duchex For Feminine Hygiene."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from and its quality fell below that which it purported and was represented to possess, namely, germicidal.

Misbranding, Section 502 (a), the following labeling statements were false and misleading since the article was not germicidal: (Carton) "Duchex represents the most advanced scientific preparation for Feminine and Marriage Hygiene. * * * what germicide is best * * * Duchex is * * * very effective * * * killing contacted germ life. * * * Its basic germicidal ingredient is Sodium Para Toluene Sulphon Chloramide which is accepted by the American Medical Association. Bacteriological Tests prove this ingredient 54 times more powerful and 288 times faster than any Phenol solution harmless to body tissues. * * * The ideal personal germicide * * * Duchex is powerful and quick acting * * * for * * * killing germ life it contacts. * * * with no unpleasant disinfectant odor. * * * Modern Physicians and experienced Nurses recommend medicated douching at least three times weekly for * * * good health"; (envelope) "Duchex is * * * very, very effective for * * * killing contacted germ life. Its germicidal ingredient, (Sodium Para Toluene Sulphon Chloramide) is accepted by the American Medical Association."

DISPOSITION: May 28, 1945. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.